A-035 US
PATENT APPLICATION

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:			
Applicant:	**Trogolo et al.**		
Serial No.:	**10/032,372**	**Examiner:**	**F. I. Choi**
Filed:	**December 21, 2001**	**Art Group:**	**1616**
Title:	**Encapsulated Inorganic Antimicrobial Additive for Controlled Release**		

DECLARATION OF FRANK C. ROSSITTO PURSUANT TO 37 CFR 1.132

I, Frank C. Rossitto, hereby declare as follows:

I am Polyurethane Product Line Manger for Bostik, Inc., of Middletown, MA, and have held this position for approximately 5 years.

I hold a Ph.D. in Organic Chemistry from the University of Massachusetts, in Amherst, MA and a B.S. in Chemistry from the University of New Hampshire in Durham, NH. I have published more than 10 papers in various journals and proceedings, including the Polyurethanes World Congress.

I have nearly fourteen years experience in the field of polyurethanes and have been intimately involved in all facets of polyurethane chemistry, processing and manufacture and continue to have a hands-on role in polyurethane product and process development and engineering.

I am a co-inventor of the invention disclosed in and embraced by the claims of the above-referenced pending US patent application. I am aware of the arguments being put forth in rejecting this application and, in particular, those relating to Japanese Patent Publication No. 4-66512 and its supposed teachings.

In response to the assumptions and conclusions reached by the Patent Office in the prosecution of this application, particularly in relation to JP 4-66512, I wish to make the following statements and observations based on my extensive experience in the art.

Hydrophilic v. Hydrophobic Polymers

There is no clear demarcation as between hydrophilic and hydrophobic polymers: the two classes overlap to an extent as water absorption characteristics (hydrophilic) and water repellant characteristics (hydrophobic) are spoken of in relative terms: oftentimes with respect to the same polymers. Typically, though, those polymers whose water content is at least 2% by weight, as determined by ASTM D570, are considered hydrophilic, though even these are weakly hydrophilic. Relative to utility in the present invention, suitable hydrophilic polymers must have a water content of at least 5% by weight and, preferably, at least about 20% by weight in order to ensure adequate water absorption and ion-exchange and transport. Polymers having this degree of water content, particularly the latter, are certainly not hydrophobic and, as discussed below, would not be used to modify a hydrophilic additive where the purpose of the modification is to mask the hydrophilic properties of the additive itself.

Relative to the present invention, it is also important to note that hydrophilic polymers have an inherent tendency to be in equilibrium, relative to water content, with their environment. Thus, variation in the concentration of moisture in the environment in which the hydrophilic polymer is placed will affect its absolute water content at any given point in time. In following, in moving a hydrophilic polymer from a dry environment to a moist environment or, similarly, taking a dried hydrophilic polymer and allowing it to stand in ambient conditions will cause the hydrophilic polymer to absorb moisture from the air, if present, until equilibrium is regained. Water absorption is not contingent upon immersion in water; although, it will be expedited and maximized by water immersion. Thus, as discussed below, were the polyurethane of JP 4-66512 hydrophilic, water absorption would have taken place since the conditions under which the hydrated zeolite particles were coated were sufficient to drive off water (>150°C for >20 minutes) and, hence, the zeolite and polyurethane, if hydrophilic, would have endeavored to regain equilibrium. This would have been especially true for the zeolite unless the zeolite were unable to absorb moisture: a happenstance consistent with a hydrophobic coating precluding water from reaching the zeolite.

Modification of Hydrophilic Inorganic Additives

Small particle size inorganic additives, especially those in the micron and submicron range, are very difficult to incorporate into liquids and molten polymer materials, especially in a homogeneous manner. This difficulty is markedly exacerbated with those inorganic additives that are hydrophilic or whose surface is hydrophilic. Hydrophilic properties, especially adsorbed water, tend to cause the inorganic particles to agglomerate or clump together making their dispersion very difficult if not impossible.

It is well known and an established practice in the art to improve the dispersability of hydrophilic particles through surface modification of the particles themselves in order to render them hydrophobic. Typically this is accomplished either by chemical reaction, wherein the surface characteristics are chemically altered to a hydrophobic nature, or by masking or coating the particles with a hydrophobic material so as to present a hydrophobic surface. Silanes are perhaps the most common materials used to treat hydrophilic additives; however, other hydrophobic materials, like hydrophobic polyurethanes, are also used or taught.

Based on my experience, it would have been counterproductive for JP 4-66512 to have used a hydrophilic treatment, as suggested by the Patent Office, as even weakly hydrophilic polymer particles will have a tendency to be attracted to one another and agglomerate. This would be especially true for polymers whose degree of hydrophilicity is 5% by weight or more. Certainly, strongly hydrophobic, weakly hydrophilic materials could be used; however, such materials would not be capable of use in the practice of the present invention as they would be incapable of absorbing sufficient water to enable adequate release of an antimicrobially effective amount of the antimicrobial agent.

Discussion of JP 4-66512

JP 4-66512 is concerned with improving the dispersability of hydrophilic inorganic antimicrobial agents, specifically silver zeolites, in hydrophobic polymer resins. As noted above, hydrophilic inorganic additives are very difficult to disperse in most any matrix due to their strongly hydrophilic nature and inherent tendency to agglomerate and clump together, especially in the presence of moisture. JP 4-66512 has elected to mask the hydrophilic properties by coating the individual particles with an extremely thin (< 0.08μ) coating of polyurethane. The Patent Office has asserted that the polyurethane is hydrophilic, yet has provided no proof or evidence thereof. To the contrary, based on the state of the art and the intended objective as well as a close reading of JP 4-66512, it is my educated conclusion that the polyurethane is not hydrophilic, and certainly not hydrophilic to the extent necessary for use in the practice of our invention.

While evaluation of the polyurethane of JP 4-66512 would definitively resolve the issue, personal efforts to secure information about the polyurethane, especially the Nippolane 1100 polyol, which would be the component responsible for any hydrophilic properties, as well as samples of these materials have been unsuccessful to date. Nevertheless, there is ample evidence to conclude that the materials are non-hydrophilic insofar as the present invention is concerned.

First, as noted above, the use of a hydrophilic material, at least one that would be suitable for use in the practice of the present invention, would be contrary to the practice in the art and, more importantly, would be contrary to and frustrate the very purpose of the invention of JP 4-66512.

Second, the water content was lower for those particles having 3% by wt. polyurethane as opposed to those having just 1.5% by wt. polyurethane: a result that is consistent with a dilutive effect of adding a hydrophobic resin to a hydrophilic material as well as with a hydrated material that has been subjected to a longer processing time at the elevated temperature.

Third, JP 4-66512 specifically calls for a non-hygroscopic polyurethane and demonstrates that its polyurethane does not absorb moisture even after having been subjected to conditions that would have driven moisture from it. Certainly, if nothing else, water uptake would have been noted in the zeolite, if it were able to do so. The fact that none was seen indicates that the zeolite was prevented from absorbing water: a result consistent with a hydrophobic coating.

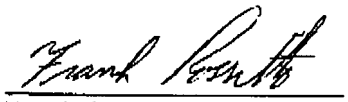
Fourth, the sharp and marked drop in ion release associated with the thicker coating, even though the coating thickness increased by less than 0.05μ, is fully consistent with a hydrophobic coating.

Conclusion

Despite the contention of the Patent Office that the polyurethane employed in JP 4-676512 was hydrophilic, there is nothing whatsoever to support such a hypothesis and, in fact, all indications are that it is not hydrophilic. The art, particularly in light of the objective and intent of JP 4-66512, teaches the use of a hydrophobic polymer. Even the discussion and properties set forth in JP 4-66512 relative to the polyurethane encapsulated zeolite particles points to a non-hydrophilic polyurethane. In light of these many factors, the only conclusion is that the material is not a hydrophilic polyurethane.

I hereby state that all statements made herein of my knowledge are true, all statements made herein on information and belief are believed to be true and all statements made herein are made with the knowledge that whoever, in any matter within the jurisdiction of the Patent and Trademark Office, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false wiring or document knowing the same to contain any false, fictitious or fraudulent statements or entry, shall be subject to the penalties set forth under 18 USC 1001, and that violations of this paragraph may jeopardize the validity or enforceability of any patent resulting therefrom.

Respectfully submitted



Frank C. Rossitto, PhD
Bostik, Inc.
Middletown, MA 01880
781-224-7104